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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,832	02/27/2002	Mustapha Abdelouahed	1440.1038-003	5718

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EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/084,832

Applicant(s)

ABDELOUAHED ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on June 28, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 and 37 is/are allowed.
- 6) ☒ Claim(s) 1-7, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

1. In view of the appeal brief filed on June 28, 2004, PROSECUTION IS HEREBY REOPENED. A new Office Action on the merits are set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 34 is indefinite in the recitation of a "ternary complex reactive antibody". This phrase is not one which has a universally accepted meaning in the art, therefore it is no way for the person of skill in the art to ascribe a discrete and identifiable class of antibodies to said phrase.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated complex comprising heparin and the heparin binding platelet factor 4 and thrombospondin-1, wherein each of the heparin binding proteins is an intact protein isolated from human platelets or produced using recombinant means, or a recombinant protein, a variant recombinant, or is a synthetic protein, does not reasonably provide enablement for any and all biologically active fragments prepared from a protein isolated from human platelets. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. In addition, the office does not have the facilities for examining and comparing any and all biologically active fragments that will bind with the isolated complex without undue experimentation. In the absence of evidence to the contrary, the burden is upon the applicant to show support for this limitation to obviate this rejection.

6. Prosecution on the merits of this application is reopened on claims 1-7 and 34-35 considered unpatentable for the reasons indicated below:

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gogstad et al (British Journal of Haematology, April 1983, Vol 53, No. 4, pages 563-573).

Claims 1-7 are broadly drawn to a product comprising an isolated complex comprising heparin and heparin binding proteins, which includes platelet factor 4 and thrombospondin-1. Gogstad et al teaches immobilized heparin and platelet proteins in buffer solutions and antibodies against platelet proteins (page 564 and 565, materials and methods). Platelet factor 4, thrombospondin and G4 platelet proteins exhibited affinity to heparin (intact protein). These proteins were isolated by immunoelectrophoresis, which formed peaks to indicate binding (summary).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gogstad et al (British Journal of Haematology, April 1983, Vol 53, No. 4, pages 563-573) in view of Foster et al (USP#4,281,061).

The kit is drawn to a buffered medium comprising heparin; a buffered medium comprising isolated human PF4; a buffered medium comprising isolated human TSP-1. Gogstad et al teaches immobilized heparin and platelet proteins in buffer solutions and antibodies against platelet proteins (page 564 and 565, materials and methods). Platelet factor 4, thrombospondin and G4 platelet proteins exhibited affinity to heparin. These proteins were isolated by immunoelectrophoresis, which formed peaks to indicate binding (summary). The reference of Gogstad et al does not teach these reagents in a kit format.

However, kits are well known embodiments for assay reagents. Foster et al describe one example. In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. See Figure 6 and column 15, lines 10-34.

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the reference of Gogstad et al and format them into a kit because Foster teach the convenience of a kit and how the can enhance sensitivity of a method by providing reagents as a kit. The reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing and assay method. One of ordinary skill in the art would have been motivated to formulate this teaching into a kit format to study

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the binding relationship of platelet proteins to heparin in a laboratory or academic setting. With respect to the recitation of "a standardized positive control comprising known amounts of ternary complex reactive antibody" in claim 34, applicant has not defined this ternary complex reactive antibody, therefore it is the examiner's position that the antibody of Gogstad et al reads on applicant's ternary complex reactive antibody.

### ***Allowable Subject Matter***

11. Claims 36-37 are allowed.

12. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach nor suggest an isolated ternary complex comprising heparin, platelet factor 4 and thrombospondin-1.

### ***Conclusion***

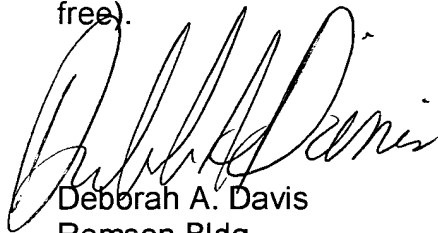
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-

free).



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March 7, 2005



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03/25/05